

Appl. No. : 10/698,148
Filed : October 31, 2003

REMARKS

Status of the Claims

Claims 43-50, 52, and 54-75 stand pending. Claims 51 and 53 were previously cancelled. Claims 62-71 and 74-75 have been previously withdrawn.

Claim 43 is amended herein to recite "attaching the proximal end at the attachment site without creating a serosal to serosal bond, such that the sleeve is configured to deliver food from the esophagus directly into the intestine." Written description support for the amendment can be found, for example, at Figure 46B and paragraph [0363] of the specification as published. No new matter has been added.

Rejections under 35 U.S.C. § 103(a)

Bessler in view of Pugsley.

Claims 43-50, 52, 54-61 and 72-73 are rejected under 35 U.S.C. § 103(a) as unpatentable over Bessler in view of Pugsley.

The Examiner has not made a *Prima Facie* Case of Obviousness

As stated in the M.P.E.P. § 2142, in order to establish a *prima facie* case of obviousness, the references when combined must teach or suggest all of the claim limitations. The Examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. M.P.E.P. § 2142. Applicants respectfully disagree with the rejection, and submit that the Examiner has not made a *prima facie* case of obviousness because even when the references are combined, the combination does not teach the invention as claimed, and amended herein.

Moreover, because of the disparate objectives of the two references, one skilled in the art would have no reason to make the proposed combination.

Applicants' claimed invention recites, *inter alia*, a method in which the sleeve is both 1) attached without creating a serosal to serosal bond, and 2) attached using a tissue piercing anchor with a proximally facing surface which rests against the serosal surface.

Bessler discloses a gastric bypass "stent" 2 comprising a stent member 4 at the proximal end 6 of a tubular member 8 (paragraph [0018]). Bessler fails to teach or suggest attaching the proximal end of a gastrointestinal sleeve using at least one tissue penetrating anchor having a

distal end which includes a proximally facing surface which rests against a serosal surface to retain the sleeve.

Pugsley fails to make up for this deficiency. Pugsley has nothing to do with attaching a gastrointestinal sleeve as in Applicants' claimed invention. Pugsley instead discloses a method and apparatus for folding tissue to bring two areas of serosal tissue into contact with each other across a plication to repair a lower esophageal sphincter (Abstract). As shown in Fig. 9 of Pugsley, a collagen-impregnated tissue anchor 210 is pinched between the two opposing serosal surfaces of the tissue plication to accelerate the creation of a serosal-to-serosal bond. This produces an irreversible change to the anatomy of the patient.

Thus, combining Bessler with Pugsley would result in a gastric bypass stent as disclosed in Bessler secured to a dual-walled tissue plication wherein the second collagen-impregnated anchor 210 of Pugsley would necessarily result in the creation of a serosal-to-serosal tissue bond. This is expressly excluded from the scope of Claim 43 as amended herein. As the combination of references fails to teach or suggest each and every claim element, the Examiner has not made a *prima facie* case of obviousness. Thus, Applicants request that the rejection be withdrawn.

One of Ordinary Skill Would Have No Reason to Combine and Further Modify the References

In the Court's recent decision in *KSR International Co. v. Teleflex Inc.*, 550 U.S. _____ (2007), the Court repeatedly emphasized the value of determining if there is any "reason to combine" the various teachings in the art. The Court noted that "[a] patent composed of several elements is not proved obvious merely by demonstrating that each element was, independently, known in the prior art." (*KSR*, Syllabus, page 4 and page 14).¹ Thus, the Court has made it abundantly clear that some reason to combine the various elements must be present in order to establish a *prima facie* case of obviousness.

Applicants respectfully submit that one of skill in the art would have absolutely no reason to add transmural attachment anchors which are movable from a reduced cross section to an

¹ The Court also noted that "it can be important to identify a reason that would have prompted a person of ordinary skill in the art to combine the elements as the new invention does." (*KSR*, Syllabus, page 5; see also, page 15). Additionally, the Court noted that "inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." (*KSR*, page 15).

enlarged cross section to the disclosure of Bessler. To the contrary, Bessler teaches a nonpuncturing attachment system, in the form of a self expandable or balloon expandable stent. Tissue penetration generally as a way to attach devices (e.g., sutures, clips etc.) was known at the time of Bessler, so Bessler's omission in this context is a clear suggestion against the use of penetrating anchors. Even assuming arguendo that one would add a puncturing tissue fastener as described in Pugsley to Bessler's stent, the result would be a sleeve attachment to a plication which permanently results in a serosa to serosa bond. That is expressly outside of the scope of Claim 43.

As stated in Applicants' disclosure, serosal tissue in contact with itself when creating a plication (as shown, for example, in Figs. 8-9 of Pugsley), with both ends of a tissue fastener (e.g., first anchor 220 and third anchor 205 of Pugsley) resting against mucosal tissue tends to heal together to form a seal (also see, e.g., paragraph [0358] of the present application). This fusion of two serosal layers together can cause an irreversible change to a patient's anatomy. Attaching the walls of the esophagus and fundus together as disclosed in Pugsley, as well as adding a collagen irritant is known to promote serosa to serosa tissue healing, thereby making the plication permanent.

In contrast, attaching the proximal end of Applicants' gastrointestinal sleeve without creating a serosal-to-serosal bond, and when the proximally facing surface of the distal end of the tissue anchor rests against a serosal surface to retain the sleeve as claimed (and as illustrated, for example, in Fig. 46B of Applicants' disclosure), the anchor can advantageously be removed at a later date without changing the patient's anatomy. Unlike the serosal to serosal plication created by Pugsley's device, Applicants' method avoids the need for two serosal layers to come in direct contact with each other.

Secondary Factors Support A Finding of Non-Obviousness

Secondary considerations must be considered in every case where they are presented. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983); *KSR International Co. v. Teleflex Inc.*, 550 U.S. ____ (2007). These include factors such as unexpected results, long-felt need, and failure of others. *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1380 (Fed. Cir. 1986); *Graham v. John Deere*, 383 U.S. 1 (1966); *In re Sullivan*, No. 2006-1507

(Fed. Cir. 2007)(holding the PTO is obligated to consider applicant evidence of secondary consideration in cases where obviousness is at issue). A *prima facie* case of obviousness can also be rebutted if the applicant can show that the art in any material respect taught away from the claimed invention. *In re Haruna*, 249 F.3d 1327 (Fed. Cir. 2001).

Teaching Away

Bessler discloses that his device is advantageous as less traumatic than previous surgical techniques (paragraph [0005]). All disclosed embodiments of Bessler's device, involve an expandable stent 4 (Fig. 1) that does not penetrate any tissue walls to meet its objective of securing the ends of the device within the esophagus. In general, the teachings of Bessler would lead one of skill in the art in the direction of a non-penetrating anchoring system, such as a balloon expandable or self expanding stent as disclosed therein. Thus, Applicants submit that Bessler tends to teach away from the use of a penetrating tissue attachment, and that the use of Pugsley's penetrating tissue fastener to secure Bessler's bypass stent would be contrary to Bessler's intent of providing a less traumatic device for gastric bypass.

Gannoe in view of Pugsley

As noted above and stated in the M.P.E.P. § 2142, in order to establish a *prima facie* case of obviousness, the references when combined must teach or suggest all of the claim limitations. The Examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. M.P.E.P. § 2142. Applicants respectfully disagree with the rejection, and submit that the Examiner has not made a *prima facie* case of obviousness because even when the references are combined, the combination does not teach the invention as claimed.

The Examiner has not made a *Prima Facie* Case of Obviousness

Gannoe discloses methods and devices for creating a tissue ring such as in the upper stomach. As shown in Fig. 5E of Gannoe, use of the disclosed device results in acquiring tissue folds in a circumferential configuration within a hollow body organ (Abstract) with mucosal tissue on both external surfaces of the placcation, and serosal tissue "sandwiched" in between the mucosal layers. This results in each end of the staple being attached to a mucosal surface of

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tissue. Attachment of a bypass conduit 113 at the GEJ at the tissue ring, as shown in Fig. 5E of Gannoe, results in each end of the staple resting against mucosal tissue of a circumferential tissue fold. Just like Pugsley, Gannoe seeks a permanent serosa-serosa bond to hold a plication in place.

As noted above, Pugsley's tissue fastener is used to create a multi-layer tissue plication, where Pugsley's collagen-impregnated anchor 210 further facilitates serosal to serosal bonding. Thus, combining Gannoe with Pugsley would result in a gastric bypass stent wherein Pugsley's anchor 210 is "sandwiched" between serosal surfaces, facilitating serosal to serosal bonding, contrary to the recitation of Claim 43 of "attaching the proximal end [of the gastrointestinal sleeve] at the attachment site without creating a serosal to serosal bond." Since the combination of references fails to teach or suggest each and every claim element, the Examiner has not made a *prima facie* case of obviousness. Thus, Applicants request that the rejection be withdrawn.

One of Ordinary Skill Would Have No Reason to Combine and Further Modify the References

Even assuming arguendo the combination of Gannoe and Pugsley could be further modified to arrive at the claimed invention, Applicants submit that one of ordinary skill in the art would have no reason to do so, e.g., attaching the proximal end of the gastrointestinal sleeve at an attachment site without creating a serosal to serosal bond. As noted above and shown in Figs. 5A-5E of Gannoe, Gannoe teaches a mucosal to mucosal puncture of a plication, for the purpose of both reducing the diameter of the opening at the base of the esophagus and permit serosa to serosa bonding to enable a lasting clinical result. This disclosure would not give one of ordinary skill in the art any reason to eliminate the plication which is contained in every embodiment disclosed in Gannoe, and instead use the method claimed, which would defeat Gannoe's objective of obtaining permanent serosa to serosa healing. Furthermore, an attachment step that does not result in serosal to serosal bonding as recited in Claim 43 would according to Gannoe not result in the acquisition of a sufficiently secure circumferential tissue fold and thus render Gannoe's device unsuitable for its purpose, and act as a disincentive to the combination proposed by the Examiner. *See Tec Air Inc. v. Denso Mfg. Michigan Inc.*, 192 F.3d 1353, 1360 (Fed. Cir. 1999)(if a proposed modification would render the prior art device being modified unsuitable for its intended purpose, the proposed modification would not have been obvious).

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Claim Objections

The Examiner objected to Claim 52, finding that the recitation of a "T-tag" is overly broad, indefinite, unclear, and fails to particularly point out what applicant considers his invention or any corresponding structure. Applicants disagree, and submit that a "T-tag" is both understood in the art, and is clearly defined in the disclosure. Furthermore, Applicants respectfully note that the Examiner has not yet addressed Applicants' arguments as set forth in previous responses and reproduced below, in support of withdrawal of the rejection.

For example, paragraph [0166] of Applicants' specification, states in part that a "T-tag is basically a cross member or "T" that is attached to an elongated member or tail at or near the mid-point of the T." As recited in paragraph [227], "the purpose of the T in a T-fastener is to distribute and resist the forces that could act to pull it through the tissue, in this case the gastric wall".

In general, the T-tag is one way of providing a serosal surface footprint which resists retraction through the stomach wall. The anchor passes transmurally from inside the tissue wall to outside the wall in a reduced cross-sectional configuration (*e.g.* by orienting the cross bar on the T into parallel with the axis of penetration) and enlarges (*e.g.* by inclining the cross bar on the T into parallel with the serosal surface) following deployment. As recited in paragraph [0166], "T-tag fasteners are generally configured to flex at the juncture of the T and tail to allow delivery along the axis of the T through a minimal puncture diameter."

Applicants respectfully request that this objection be withdrawn.

Co-Pending Applications of Assignee

Applicant wishes to draw the Examiner's attention to the following co-pending applications of the present application's assignee.

Serial Number	Title	Filed
10/998,424	Apparatus and Methods for Treatment of Morbid Obesity	11/29/2004
11/025,364	Devices and Methods for Treating Morbid Obesity	12/29/2004
11/124,634	Devices and Methods for Attachment of an Endolumenal Gastrointestinal Implant	05/05/2005
11/431,040	Methods of Transmural Attachment in the Gastrointestinal System	05/09/2006

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11/430,677	Attachment System for Transmural Attachment at the Gastroesophageal Junction	05/09/2006
11/431,054	Methods of Adjusting Therapy in a Patient Having an Endolumenal Bypass to Treat Obesity	05/09/2006
11/400,724	Devices and Methods for Endolumenal Gastrointestinal Bypass	04/07/2006
11/430,275	Everting Gastrointestinal Sleeve	05/08/2006
11/430,278	Attachment Cuff for Gastrointestinal Implant	05/08/2006
11/430,274	Cuff and Sleeve System for Gastrointestinal Bypass	05/08/2006
11/429,934	Gastrointestinal Implant System	05/08/2006
11/548,605	Devices and Methods for Endolumenal Gastrointestinal Bypass	10/11/2006
10/903,255	Gastrointestinal Sleeve Device and Methods for Treatment of Morbid Obesity;	07/30/2004
11/236,212	Devices and Methods for Attachment of a Gastrointestinal Sleeve	09/27/2005
11/123,889	Devices and Methods for Gastric Surgery	05/06/2005
11/125,820	Suction Assisted Tissue Plication Device and Method of Use	05/10/2005
11/789,561	Methods and Devices for Gastrointestinal Stimulation	04/25/2007
11/861,156	Toposcopic Access and Delivery Devices	09/25/2007
11/861,187	Toposcopic Methods and Devices for Delivering an Elongate Sleeve Having Axially Compressed and Elongate Configurations	09/25/2007
11/861,172	Methods for Toposcopic Sleeve Delivery	09/25/2007

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history

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shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

CONCLUSION

In light of the foregoing remarks, Applicants respectfully submit that the present application is in condition for allowance. If any matters should remain, the Examiner is invited to contact the undersigned at the telephone number provided below. Please charge any fees, including any fees for additional extensions of time, or credit overpayment to Deposit Account No. 11-1410.

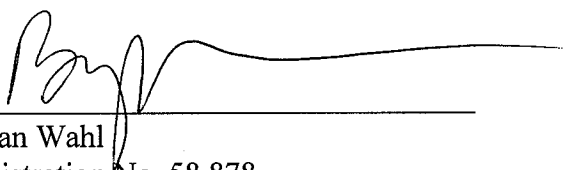
Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: _____

5/9/08

By: _____


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